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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/072,464 | 02/07/2002 | Gregory R. Collins | 1508/1124US1 | 1828 |

7590 03/27/2003
DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

EXAMINER

KIM, SUN U

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1723

DATE MAILED: 03/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,464

Applicant(s)

COLLINS ET AL.

Examiner

John Kim

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 18 and 37-40 is/are rejected.
- 7) ☒ Claim(s) 7-17, 19-36 and 41-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 18 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/06292. WO 00/06292 teaches a hemodiafiltration method and system comprising a first conduit having a first end and an opposing second end, the first end (41) receiving first fluid from dialysis machine (43) and the second end (420) for discharging dialysate fluid to the dialysis machine (43) and second conduit (2) in selective communication with the first conduit (41) to divert amount of first fluid from the first conduit (41) through at least one sterilizing filter (11, 13) to produce a substitution fluid and control unit (40) responsive to flow rate of first fluid via a flow meter (10) and a flow rate of blood via a flow meter (26) to control a substitution fluid pump (8) wherein the control unit also receives signals from pressure sensors (9, 132) which are located upstream and downstream of substitution fluid pump (see figure 1; page 3, lines 19-21; page 7, line 7 – page 12, line 25). Claims 1-6, 18, and 37-40 essentially differ from the apparatus and method of WO 00/06292 in reciting that control unit prevent flow of the substitution fluid to the extracorporeal circuit when the flow rate of first fluid or dialysate fluid and the flow rate of blood meet a prescribed criteria. WO 00/06292 teaches that control unit (40) receives inputs from various components of the hemodiafiltration device e.g. pressure transducers, flow meters, flow switches, etc. and controls various system functions such as setting values for pump speeds, opening/closing valves (see page 12, lines 20-25). It would have been obvious to a person in ordinary skill in the art to control the substitution fluid pump to prevent flow of substitution fluid

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to the extracorporeal circuit when the flow rate of first fluid or dialysate fluid and the flow rate of blood meet a prescribed criteria to carry out desired hemodiafiltration process.

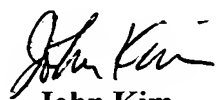
3. Claims 7-17, 19-36 and 41-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
March 22, 2003